

10/551277

JC09 Rec'd PCT/PTO 28 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No. : PCT/US2004/009605
International Filing Date : 29 March 2004 (29.03.2004)
Earliest Priority Date : 28 March 2003 (28.03.2003)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : IMPROVED BRAIDED MESH CATHETER

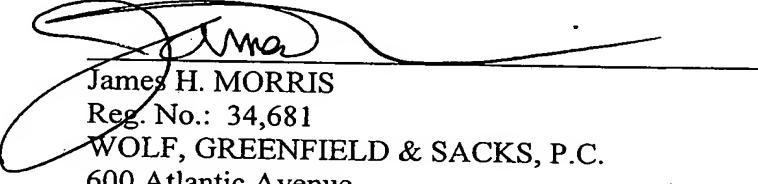
Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing a Demand for International Preliminary Examination,
Amendments under Article 34 and Fee Calculation Sheet with Deposit Account
Authorization.

A check in the amount of \$923.00 is enclosed to cover the fee. If this is insufficient, please
charge any deficiency, or credit any overpayment in the total fees, to the account of Wolf,
Greenfield & Sacks, P.C., Deposit Account No. 23/2825.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application
Branch is respectfully requested to contact the undersigned collect at (617) 720-3500, Boston,
Massachusetts.

Respectfully submitted,


James H. MORRIS
Reg. No.: 34,681
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
Facsimile: (617) 720-2441

DOCKET NO.: B1075.70043

DATE: 04 April 2005

x 4/3/05

Express Mail Label No.: EL960700818US

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of the Authority may be indicated by the applicant on the line below:

IPEA/US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty

For International Preliminary Examining Authority use only

Identification of IPEA	Date of Receipt of DEMAND
------------------------	---------------------------

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference B1075.70043
International Application No. PCT/US2004/009605	International Filing Date (day/month/year) 29 March 2004 (29.03.2004)	(Earliest) Priority date (day/month/year) 28 March 2003 (28.03.2003)

Title of Invention
IMPROVED BRAIDED MESH CATHETER

Box No. II APPLICANT(S)		Telephone No.:
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) C.R. BARD, INC. 730 Central Avenue Murray Hill, New Jersey 07974 United States of America		Facsimile No.:
		Teleprinter No.:

State (that is, country) of nationality: US	State (that is, country) of residence: US
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) BROWN, III, Charles E. 36 14th Avenue Haverhill, Massachusetts 01830 United States of America	

State (that is, country) of nationality: US	State (that is, country) of residence: US
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) CHIAVETTA, Amedeo 1 Don Mac Drive Derry, New Hampshire 03038 United States of America	

State (that is, country) of nationality: US	State (that is, country) of residence: US
X Further applicants are indicated on a continuation sheet.	

Form PCT/IPEA/401 (first sheet) ((January 2004)
Express Mail Label No. EL960700818US

See Notes to the demand form

Sheet No. 2		International application No. PCT/US2004/009605
Continuation of Box No. II APPLICANT(S)		
<i>If none of the following sub-boxes is used, this sheet is not to be included in the demand.</i>		
Name and address: <i>(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)</i>		
<p>KOZEL, Peter D. 519 Bedford Street Concord, Massachusetts 01742 United States of America</p>		
State (i.e. country) of nationality: US	State (i.e. country) of residence: US	
Name and address: <i>(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)</i>		
<p>LAMSER, Dennis 60 Pleasant Street Arlington, Massachusetts 02476 United States of America</p>		
State (i.e. country) of nationality: US	State (i.e. country) of residence: US	
Name and address: <i>(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)</i>		
<p>THERRIAULT, Glenn 226 Bishop Street Attleboro, Massachusetts 02703 United States of America</p>		
State (i.e. country) of nationality US	State (i.e. country) of residence: US	
Name and address: <i>(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)</i>		
State (i.e. country) of nationality:	State (i.e. country) of residence:	

Further applicants are indicated on another continuation sheet.

Form PCT/IPEA/401 (continuation sheet) (January 1994; reprint January 1997) See Notes to the demand form

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is agent common representative

And has been appointed earlier and represents the applicant(s) also for international preliminary examination.
 is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
 is hereby appointed, specifically for the procedure before the International Preliminary Examining Attorney, in addition to the agent(s)/common representative appointed earlier.

Name and address: (*Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.*)

MORRIS, James H.
 Wolf, Greenfield & Sacks, P.C.
 600 Atlantic Avenue
 Boston, Massachusetts 02210
 United States of America

Telephone No.:
 (617) 720-3500

Faxsimile No.:
 (617) 720-2441

Teleprinter No.:

Address for Correspondence: Mark this check box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

the international application as originally filed

the description as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004
 as amended under Article 34

the claims as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004
 as amended under Article 19 (together with any accompanying statement)
 as amended under Article 34

the drawings as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004
 as amended under Article 34

2. The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. The applicant wishes the start of the international preliminary examination to be postponed until the expiration of the applicable time limit under Rule 69.1(d).

4. The applicant wishes the start of the international preliminary examination to start earlier than the expiration of the applicable time limit under Rule 69.1(d).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: . . . English

which is the language in which the international application was filed.
 which is the language of a translation furnished for the purposes of international search.
 which is the language of publication of the international application
 which is the language of the translation to be furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.

Box No. VI CHECKLIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|--|---|----------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | 2 sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | 6 sheets |
| 6. other (specify) | : | sheets |

For International Preliminary Examining Authority use only

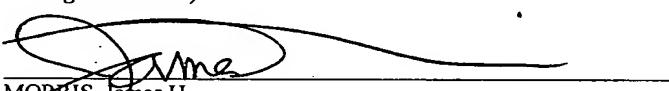
Received	not received
<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input checked="" type="checkbox"/> other (specify):
Transmittal letter
Postcard
Check |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).



MORRIS, James H.

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

- | | |
|--|---|
| 3. <input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. | <input type="checkbox"/> The applicant has been informed accordingly. |
| 4. <input type="checkbox"/> The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5. | |
| 5. <input type="checkbox"/> Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82. | |
| 6. <input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8 below, does not apply. | |
| 7. <input type="checkbox"/> The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5. | |
| 8. <input type="checkbox"/> Although the date of receipt of the demand is after the expiration of the time limit under Rule 54Bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82. | |

For International Bureau use only

Demand received from IPEA on:

Form PCT/IPEA/401 (last sheet) (January 2004)

See Notes to the demand form

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

For International Preliminary Examining Authority use only

International
Application No. PCT/US2004/009605Applicant's or agent's
File reference: B1075.70043

Date stamp of the IPEA

Applicant

C.R. BARD, INC. ET AL.

Calculation of prescribed fees

1. Preliminary examination fee

\$750.00
(USPTO
was not
ISA) P

2. Handling fee

\$173.00 H3. Total of prescribed fees
Add the amounts entered at P and H
and enter total in the TOTAL box\$923.00
TOTAL

Mode of Payment

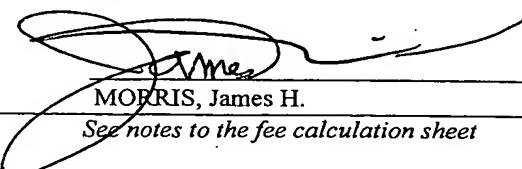
 authorization to charge deposit account with the IPEA (see below) cash cheque revenue stamps postal money order coupons bank draft other (specify):

Deposit Account Authorization (this mode of payment may not be available at all IPEAs)

The IPEA/US is hereby authorized to charge the total fees indicated above to my deposit account. (*this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit*) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

23/2825

04 April 2004


 MORRIS, James H.
See notes to the fee calculation sheet

Deposit Account Number

Date (day/month/year)

Form PCT/IPEA/401 (Annex) (July 1998; reprint January 2000)

10/551277

JC09 Rec'd PCT/PTO 28 SEP 2005

IN THE UNITED STATES PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY

International Application No. : PCT/US2004/009605
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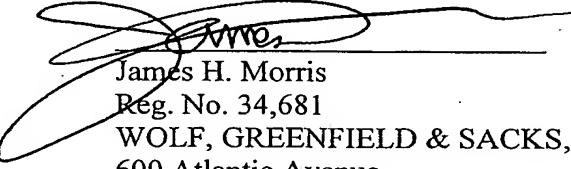
Authorized Officer : Hans Pettersson

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Alexandria, VA 22313-1450

**RESPONSE TO WRITTEN OPINION
AMENDMENT UNDER PCT ARTICLE 34(2)(b)**

Transmitted herewith is a Response to the Written Opinion mailed January 3, 2004. The following documents are included: the Amendments Under Article 34(2)(b) (5 pages) and substitute sheet pages 52 and 60 (2 pages).

Respectfully submitted,



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DOCKET NO.: B1075.70043US00

DATE: 4 April 2005

x 3/4/05

**IN THE UNITED STATES PATENT OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY**

International Application No. : PCT/US2004/009605
International Filing Date : 29 March 2004 (29.03.2004)
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Title : BRAIDED MESH CATHETER

Authorized Officer : Hans Pettersson

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO WRITTEN OPINION
AMENDMENTS UNDER PCT ARTICLE 34(2)(b)**

Applicants hereby respond, pursuant to PCT Article 34(2)(b) and PCT Rule 66.3, to the Written Opinion mailed 3 January 2005 (03.01.05). The International Preliminary Examining Authority is requested to take into account the following remarks and amendments to the claims in drafting the International Preliminary Examination Report (IPER). Moreover, Applicants respectfully request, under PCT Rule 66.4, another Written Opinion and an opportunity to respond thereto, should the Examining Authority conclude that a favorable IPER cannot be issued.

LETTER UNDER PCT RULE 66.8 AND PCT INSTRUCTIONS SECTION 205(b)

Applicants submit the attached replacement sheets 52 and 60 for the original sheets with the same numbers, pursuant to Rule 66.8, and request the replacement sheets be substituted for the original sheets.

The status of the claims after the amendments is as follows:

Claims 2-65 Original.
Claim 1 Replaced by an amended claim.
Claims 66-70 Added.

REMARKS UNDER PCT RULE 66.3

Claims 1-65 were previously pending, of which claims 1-27 have been examined. Claim 1 has been replaced with an amended claim. Claims 66-70 have been added. All of the new claims are supported by the specification as originally filed, and no new matter is added. The application as now presented is believed to satisfy both the novelty and the inventive step requirements of Article 34(1) PCT.

A. Deferral of Certain Issues Raised in Written Opinion

Applicant acknowledges that several issues relating to formal matters are raised in the Written Opinion. For example, the Written Opinion states that contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in Documents D1 and D7 is not mentioned in Applicant's application. In addition, the Written Opinion states that the units "inches" and "French" employed on pages 9, 37 and 46 are not recognized in international practice, contrary to the requirements of Rule 10.1(d) PCT. Further, the Written Opinion states that the statement on page 51 results in a lack of clarity because it implies that the subject matter for which protection is sought may be different from what is defined by the claims. Because these issues are based on requirements that vary from country to country, Applicant wishes to defer resolution of several of these issues until national stage processing. Applicant thanks the Examiner for bringing the issues to Applicant's attention.

The Written Opinion also states that the claims lack unity of invention and that claims 28-37 and 49-53 relate to subject matter considered to be covered by the provisions of Rule 67.1(iv) PCT. Because the requirements relating to these objections do not apply in at least one of Applicant's designated jurisdictions (e.g., the United States), Applicant wishes to address these objections during national stage processing.

B. Novelty of Claims

The Written Opinion states that the subject matter of former independent claim 1 lacks novelty in view of document D1 (U.S. Patent No. 5,891,136). Applicant has amended claim 1 to clearly distinguish over D1 (as discussed below). The amendment to claim 1 is believed to be supported in the application as filed at page 39, lines 21-32, for example.

a. Overview of the Invention

One aspect of the present invention relates to the actuation of a braided conductive member of a catheter using a mandrel (page 39, lines 21-23). When the mandrel is slid distally within the shaft of the catheter, the braided conductive member assumes an undeployed configuration which may have a generally cylindrical shape (page 39, lines 23-25). When the mandrel is slid proximally within the shaft, the braided conductive member assumes a deployed configuration, which may have a disk-like shape (page 39, lines 27-29).

The braided conductive member is comprised of helically wound filaments that are partially insulated (page 9, lines 15-19). As a result of this helical construction, upon radial expansion of braided conductive member, the portions of filaments that are uninsulated do not contact adjacent filaments and thus, each filament remains electrically isolated from every other filament (page 9, lines 16-19).

When the braided conductive member is in the disk-like configuration, the uninsulated portions of the braided conductive member may be used to create an annular lesion at or near the ostium of the heart (page 26, lines 17-19). Specifically, external pressure may be applied along catheter shaft to achieve the desired level of contact of braided conductive member with the ostium tissue (page 26, lines 15-17). Energy is then applied to the ostium tissue in contact with braided conductive member to create the annular lesion (page 26, lines 17-19).

The above summary of one aspect of the present invention is provided merely for the Examiner's convenience, and is not intended to characterize any of the independent claims. Therefore, the Examiner is requested to not rely upon the summary characterization above, but to closely examine each of the independent claims to ensure that each distinguishes over the references of record for the reasons discussed below.

b. Discussion of Document D1

Document D1 discloses that an expandable-collapsible body 22 may be supported on a closed, three dimensional structure 44 formed by a resilient mesh 50 (Col. 10, lines 17-20). FIG. 6 illustrates the spherical, expanded geometry of the expandable-collapsible body 22 and FIG. 7 illustrates the collapsed geometry of the expandable-collapsible body 22 (FIGS. 6 and 7). According to one embodiment, the expandable-collapsible body 22, which is internally supported by a mesh structure 50, may be expanded or collapsed using a stilette 76 (Col. 12, lines 50-54). Pushing forward upon the stilette 76 extends the mesh structure 50 to

collapse the expandable-collapsible body 22 (Col. 12, lines 54-56). Pulling rearward upon the stilette 76 has the opposite effect, allowing the spline structure 46 or mesh structure 50 to assume its expanded geometry (Col. 12, lines 57-60).

c. Independent Claim 1

Independent claim 1, as amended, recites a catheter comprising a handle, a shaft portion coupled to a distal end of the handle, a tip portion, a braided conductive member coupled to the shaft portion and the tip portion, and a mandrel fixedly attached to the tip portion and slidably disposed within the shaft portion. Actuation of the mandrel expands the braided conductive member from an undeployed position in which the braided conductive member assumes a generally cylindrical configuration to a deployed position in which the braided conductive member assumes a disk-like configuration.

Document D1 does not disclose or suggest that actuation of a mandrel expands a braided conductive member from an undeployed position in which the braided conductive member assumes a generally cylindrical configuration to a deployed position *in which the braided conductive member assumes a disk-like configuration*. In addition, none of the other references of record discloses or suggests (alone or in combination) the catheter of claim 1.

In view of the foregoing, claim 1 distinguishes over Document D1. Claim 1 is also believed to distinguish over the other references of record, and is believed to satisfy the PCT requirements with respect to novelty and inventive step.

Claims 2- 27 depend from claim 1 and are believed to satisfy the PCT requirements with respect to novelty and inventive step for at least the same reasons.

C. New Claims

Claims 66-70 have been added to further define Applicant's contribution to the art. Newly added claims 66-70 are supported in the application as filed e.g., at page 9, line 8 – page 10, line 9 and FIG. 34A. These new claims are believed to patentably distinguish over the references of record.

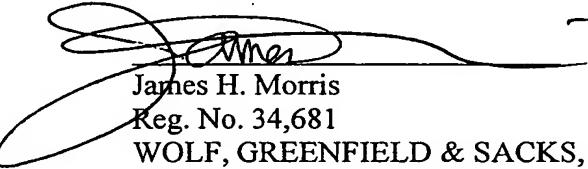
D. Conclusion

A favorable International Preliminary Examination Report in response is requested.

If for any reason this response does not place the application in condition for issuing a favorable International Preliminary Examination Report as to all claims, Applicant requests

issuance of a further Written Opinion and an opportunity to respond thereto prior to issuance of the International Preliminary Examination Report. Should there be insufficient time available for issuance for a further Written Opinion, Applicant requests the IPEA to initiate a telephone interview at Applicant's expense, and an opportunity to file a Supplemental Response to the previous Written Opinion by return fax, pursuant to PCT Article 34(2).

Respectfully submitted,



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DOCKET NO.: B1075.70043WO00

DATE: 4 April 2005

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